Survey Report

To Evaluate the Protective Effect of S-Metoprolol+ Telmisartan for Indian Patients with Hypertension

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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1 INTRODUCTION

Hypertension is a significant contributor to cardiovascular disease and mortality worldwide [1]. About one-third of the world's 8 billion people suffer from hypertension [2]. The main cause of morbidity and mortality in hypertension stems from vascular damage, affecting the heart, brain, and kidneys. Changes in the structure and function of arterial walls occur early in the disease, leading to increased arterial stiffness [3]. Hypertension is a leading risk factor for various cardiovascular conditions, including coronary artery disease, congestive heart failure, atrial fibrillation, cerebrovascular disease, peripheral arterial disease, aortic aneurysm, and chronic kidney disease [4].

Hypertension is a modifiable risk factor, and both non-pharmacological and pharmaceutical interventions can effectively mitigate the associated risks. Consequently, regular blood pressure monitoring is essential for the diagnosis and management of hypertension [5]. If lifestyle modifications cannot sufficiently lower blood pressure to target levels, medication becomes necessary. First-line treatments for hypertension include diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers (ARBs), beta-blockers, and calcium channel blockers. In many cases, patients may require a combination of two or more antihypertensive drugs to achieve their blood pressure goals [6].

Beta-blockers are a class of medications primarily used to treat cardiovascular disorders and various other medical conditions [7]. S-Metoprolol, a chirally pure betablocker, offers specific clinical advantages and appears to be beneficial in the treatment of hypertension[8].ARBs are highly effective in treating hypertension and are generally considered to have tolerability profiles comparable to placebo [9]. Among ARBs, telmisartan was reported to be preferred by almost 73% of physicians in India as a first-line agent for managing essential hypertension.

This study employs a questionnaire-based survey conducted among physicians across India to gather insights into their perspectives on the effectiveness and safety of the S-Metoprolol and Telmisartan combination therapy. Physicians' clinical experiences, patient outcomes, and adherence to treatment protocols are critical factors in assessing the real-world applicability of this combination therapy. By evaluating these perspectives, the study aimed to provide valuable data that can inform clinical practice and guide treatment strategies tailored to the Indian hypertensive population.

2 RATIONALE OF THE STUDY

The rationale for this study was to gather comprehensive insights into the clinical use and efficacy of a combination therapy of S-Metoprolol and Telmisartan in managing hypertension among Indian patients. Understanding the prescribing patterns, treatment preferences, and perceived efficacy among physicians aided in optimizing therapeutic strategies and improving patient outcomes. The purpose of this study was to evaluate the protective effect of S-Metoprolol + Telmisartan combination therapy in Indian patients diagnosed with hypertension. This investigation aimed to assess its efficacy in reducing blood pressure, improving patient compliance, and determining its long-term safety profile.

3 STUDY OBJECTIVE

The primary objective of this study was to evaluate the protective effects and clinical benefits of S-Metoprolol and Telmisartan combination therapy in Indian patients with hypertension.

4 METHODS

This cross-sectional, questionnaire-based study aimed to assess the perspectives and prescribing practices of Indian physicians regarding the S-Metoprolol and Telmisartan combination therapy for hypertension management. The study was designed to understand physicians' clinical experiences and perceptions concerning this specific treatment regimen.

Physicians managing hypertensive patients across India were identified and invited to participate through professional networks and medical associations. Participation was voluntary, and prior to their involvement, participants were provided with comprehensive information about the study's objectives and methods. An electronic survey consisting of 15 questions was employed to collect data. The survey covered areas such as demographic information of physicians, their clinical experience in managing hypertension, prescribing practices related to S-Metoprolol and Telmisartan, and perceptions regarding the clinical benefits and protective effects of this combination therapy.

Responses from participants were collected electronically and securely stored to maintain confidentiality. Subsequently, statistical analysis was conducted to summarize the findings and identify significant trends. Descriptive statistics were utilized to analyze demographic data and responses to survey questions, providing insights into prescribing patterns and physician perspectives on the therapy.

Ethical approval for this study was obtained from an Independent Ethics Committee, and it adhered strictly to the principles outlined in the Declaration of Helsinki. Participants were assured of their right to withdraw from the study at any time without facing any consequences, and all responses were anonymized to safeguard participant confidentiality.

5 RESULTS

A total of 131 HCPs participated in the survey. Below is the summary of the responses.

1. What is the percentage of HTN patients in your clinical practice?

- a. >10%
- b. 10-20%
- c. 20-30%
- d. >30%



- The majority of physicians (39.7%) reported that over 30% of patients in their clinical practice had hypertension (HTN).
- A substantial proportion of physicians (33.6%) observed that 20-30% of their patient population was affected by HTN.
- Approximately 19.1% of physicians indicated that 10-20% of their patients were diagnosed with HTN.
- A smaller percentage of physicians (7.6%) noted that less than 10% of their patient base had HTN.

2. In your opinion what is the unmet medical need in current Hypertension management? (Can mark more than 1 option, if required)

a. Aggressive blood pressure control

b. Combinations addressing different pathophysiological mechanisms responsible for increase in blood pressure

c. Decreasing risk of cardiovascular disease and end organ damage



- Majority of the physicians (58.0%) prioritized combinations addressing different pathophysiological mechanisms responsible for hypertension as their primary consideration in treatment selection.
- Approximately 21.4% of physicians focused on decreasing the risk of cardiovascular disease and end-organ damage as their main criterion for choosing antihypertensive therapy.
- A similar proportion, 20.6% of physicians, emphasized aggressive blood pressure control as their primary goal when selecting treatment options for hypertensive patients.

3. In your clinical practice, which anti-hypertensive agent do you prefer to initiate treatment?

- a. ACE inhibitor
- b. ARB
- c. Beta-Blocker
- d. CCB
- e. Diuretic



- In the clinical practice, the preferred anti-hypertensive agent for initiating treatment was the Beta blocker, chosen by 49.6% of the physicians.
- Additionally, 35.9% of the clinicians preferred to initiate treatment with an Angiotensin-Receptor Blocker (ARB) inhibitor, indicating a significant inclination towards these agents.
- Angiotensin-Converting Enzyme (ACE) inhibitor was the choice for 9.9% of the physicians, showing a moderate preference for this class of antihypertensive agents.
- Diuretics were selected by 3.1% of the physicians, reflecting a lower preference for these agents in initiating hypertension treatment.
- Calcium Channel Blockers (CCBs) were the least preferred, with only 1.5% of physicians choosing this class to initiate treatment.

• These results highlight that ARBs and Beta blockers were the predominant choices for initiating anti-hypertensive therapy in this clinical practice, collectively accounting for the majority of initial treatment preferences.

4. Which is the preferred beta-blocker to treat patients with HTN?

- a. S-Metoprolol
- b. Bisoprolol
- c. Atenolol
- d. Carvedilol
- e. Metoprolol



- The majority of physicians (58.8%) preferred Carvedilol for treatment of hypertension in their clinical practice.
- S- Metoprolol was preferred by 29.8% of the physicians, indicating a substantial secondary preference.
- A smaller proportion, 7.6%, of physicians selected Atenolol for treating HTN patients, reflecting a moderate alternative choice.
- Only 2.3% of the physicians favored Bisoprolol, showing minimal preference for this option.

• The least preferred beta-blocker was Metoprolol chosen by just 1.5% of the physicians, suggesting a very limited use in this clinical setting.

5. What is the clinical benefit being observed with the usage of S- Metoprolol over other beta-blockers in patients with hypertension?

- a. Better efficacy
- b. Better tolerability
- c. Good patient compliance



- In the clinical practice, the benefit of using S-Metoprolol over other betablockers in patients with hypertension (HTN) was assessed.
- Approximately 35.9% of physicians observed better efficacy, highlighting this as the most frequently reported advantage.
- Additionally, 32.1% of physicians reported good patient compliance, and another 32.1% noted better tolerability, indicating an equal distribution of these observed advantages among the remaining respondents.

6. Which is your preferred ARB to treat patients with HTN?

- a. Telmisartan
- b. Olmesartan
- c. Azilsartan
- d. Candesartan



- The majority of physicians (93.1%) preferred Telmisartan for treatment of hypertension in their clinical practice.
- Olmesartan was preferred by 3.8% of the physicians, indicating a substantial secondary preference.
- A smaller proportion, 1.5%, of physicians selected Candesartan for treating HTN patients, reflecting a moderate alternative choice.
- Another 1.5% of the physicians preferred Azilsartan as a ARB choice for the treatment of hypertension.

7. In your opinion what is the reason for preference of Telmisartan over other ARBs? (Can mark more than 1 option, if required)

- a. Greater BP reduction
- b. 24-hours BP control
- c. Better tolerability



- The majority of physicians (69.5%) cited 24-hour blood pressure (BP) control as the primary reason for preferring Telmisartan over other Angiotensin II Receptor Blockers (ARBs).
- A significant proportion of physicians (26.0%) preferred Telmisartan due to its greater BP reduction compared to other ARBs.
- Only 4.6% of physicians chose Telmisartan over other ARBs because of its better tolerability.

8. What percent of HTN patients would need initiation with a dual combination therapy?

- a. <25%
- b. 25-50%
- c. 50-75
- d. >75%



- The study revealed that 52.7% of physicians reported that 25-50% of their hypertensive patients required initiation with dual combination therapy.
- Approximately 34.4% of physicians indicated that 50-75% of their hypertensive patients needed to start treatment with a dual combination regimen.
- A smaller proportion of physicians (6.9%) observed that less than 25% of their hypertensive patients required dual combination therapy at initiation.
- Similarly, 6.1% of physicians reported that more than 75% of their hypertensive patients necessitated dual combination therapy as initial treatment.
- The findings demonstrated that the majority of physicians (87.1%) believed that at least 25% of their hypertensive patients required dual combination therapy at treatment initiation.

9. In your clinical practice, which is the preferred dual combination of antihypertensive drugs?

- a. Beta Blocker + ARB
- b. ARB + CCB
- c. ARB + Thiazide diuretic
- d. CCB + Thiazide Diuretic



- The majority of physicians (44.3%) preferred the combination of Beta blocker and Angiotensin II Receptor Blocker (ARB), making it the most frequently chosen dual therapy of antihypertensive drugs.
- Additionally, 35.9% of physicians preferred the combination of ARB and Calcium Channel Blocker (CCBs), indicating a significant secondary preference for this combination.
- A smaller proportion of physicians (16.0%) opted for the combination of CCBs and Thiazide diuretics, reflecting a moderate preference for this therapy.
- Only 3.8% of physicians chose the combination of CCB and Thiazide diuretic, suggesting it was the least preferred dual therapy.

10. What is/are the patient profile(s) where S-metoprolol and Telmisartan combination is preferred? (Can mark more than 1, if necessary)

- a. HTN and High heart rate
- b. Chronic coronary syndrome
- c. Patients after a recent MI
- d. Patients with HF



- The study revealed that 46.5% of physicians preferred the combination of Smetoprolol and Telmisartan for patients with hypertension (HTN) and high heart rate, making this the most common clinical scenario for its use.
- For patients with heart failure (HF), 18.6% of physicians indicated a preference for the S-metoprolol and Telmisartan combination.
- An equal proportion of physicians (18.6%) favored this combination for patients with chronic coronary syndrome.
- In the management of patients after a recent myocardial infarction (MI), 16.3% of physicians reported preferring the S-metoprolol and Telmisartan combination.

 The findings demonstrated that the S-metoprolol and Telmisartan combination was considered beneficial across various cardiovascular conditions, with the highest preference in HTN patients with concomitant tachycardia.

11. As per your opinion, what is the clinical advantage associated with the usage of FDC of SMetoprolol and Telmisartan? (Can mark more than 1 option, if required)

- a. Faster reduction of BP
- b. Better CV outcomes
- c. Improved tolerability
- d. Beneficial impact on patient compliance



- The analysis showed that 41.1% of physicians identified better cardiovascular (CV) outcomes as the primary clinical advantage associated with the fixeddose combination (FDC) of S-Metoprolol and Telmisartan.
- Approximately 24.0% of physicians reported faster reduction of blood pressure (BP) as a key benefit of this FDC.
- Improved tolerability was recognized by 19.4% of physicians as an important clinical advantage of the S-Metoprolol and Telmisartan combination.

- A beneficial impact on patient compliance was noted by 15.5% of physicians as an advantage of using this FDC.
- The findings demonstrated that physicians perceived multiple clinical benefits from the use of the S-Metoprolol and Telmisartan FDC, with improved CV outcomes being the most frequently cited advantage.

12. In your clinical practice, how much is the reduction in systolic BP (SBP) observed with SMetoprolol and Telmisartan combination over 4 weeks of therapy?

- a. Reduction of <10 mmHg
- b. Reduction of 11 15 mmHg
- c. Reduction of 16 20 mmHg
- d. Reduction of >20 mmHg



- Majority of physicians (29.5%) reported a reduction of 16-20 mmHg in systolic blood pressure (SBP) with the combination of S-Metoprolol and Telmisartan over 4 weeks of therapy, indicating significant efficacy of the combination.
- A similar proportion of physicians (29.5%) also noted a reduction of 11-15 mmHg in SBP, demonstrating a substantial therapeutic benefit of the combination over 4 weeks of therapy.

- Additionally, 24% of physicians observed a reduction of >20 mmHg in SBP with the use of combination over 4 weeks of therapy.
- A smaller percentage of physicians (17.1%) reported a reduction of <10 mmHg in SBP, indicating a less pronounced effect in a subset of patients.

13. As per your opinion, what percentage of patients achieve blood pressure goals after treatment with S-Metoprolol + Telmisartan combination?

- a. <25%
- b. 25-50%
- c. 50-75%
- d. >75%



- Majority of physicians (41.2%) believed 25-50% of patients achieved blood pressure goals after treatment with the S-Metoprolol + Telmisartan combination.
- A substantial proportion of physicians (37.4%) estimated that 50-75% of patients reached their blood pressure targets with this therapeutic regimen.
- A smaller percentage of physicians (14.5%) reported observing successful blood pressure control in over 75% of patients treated with the S-Metoprolol + Telmisartan combination.

• Only 6.9% of physicians indicated that less than 25% of patients attained their blood pressure goals with this treatment approach.

14. As per your opinion, what is the average duration of usage of S-Metoprolol + Telmisartan combination in HTN patients?

- a. Less than 6 months
- b. 6 months to 1 year
- c. >1 year to 5 years
- d. Life-long



- The majority of physicians (43.4%) reported that the combination of the S-Metoprolol and Telmisartan in hypertensive (HTN) patients was used for a duration of 6 months to 1 year, indicating a common treatment period for these patients.
- A significant proportion of physicians (28.7%) stated that the combination was used for more than 1 year to 5 years, suggesting its long-term efficacy and tolerability in managing hypertension.
- Additionally, 22.5% of physicians recommended the combination for life-long use, reflecting confidence in its sustained benefits for hypertension control over an extended period.

 A smaller percentage of physicians (5.4%) indicated that the combination was used for less than 6 months, possibly for initial or short-term management of hypertension.

15. In your opinion, how is the long-term safety profile of S-Metoprolol + Telmisartan combination therapy?

- a. Excellent
- b. Very Good
- c. Good
- d. Poor



- A significant proportion of physicians (45.5%) rated the long-term safety profile of the S-Metoprolol and Telmisartan combination therapy as excellent, indicating high confidence in its sustained safety.
- Additionally, 40.5% of physicians considered the long-term safety profile of the combination to be very good, reflecting a strong endorsement over prolonged use.
- A smaller percentage of physicians (14.0%) rated the safety profile as good, suggesting that while the combination is generally safe, there may be minor concerns or variations in patient experiences.

• No physicians rated the long-term safety profile as poor, indicating a consensus on the acceptable safety of the S-Metoprolol and Telmisartan combination.

6 SUMMARY

A survey involving 131 healthcare professionals revealed that a significant portion of their patients suffer from HTN, with 39.7% of physicians reporting over 30% of their patients affected. The primary consideration for treatment selection was combinations targeting different pathophysiological mechanisms (58.0%). Beta blockers were the most preferred initial treatment (49.6%), followed by ARBs (35.9%). Carvedilol was the favored beta-blocker (58.8%), while Telmisartan was the preferred ARB (93.1%). Most physicians (87.1%) indicated the necessity for dual combination therapy, with S-Metoprolol and Telmisartan being the most common choice, especially for patients with high heart rates (46.5%). The combination was praised for better cardiovascular outcomes (41.1%), significant blood pressure reductions, and a high safety profile, with 86% rating it as very good to excellent. The combination was commonly used for 6 months to 1 year by 43.4% of physicians, reflecting its efficacy and tolerability for long-term management of hypertension.

7 DISCUSSION

The results from the survey of physicians highlight critical insights into hypertension management among Indian patients. A significant proportion of physicians (39.7%) reported that over 30% of their patients have hypertension, emphasizing the urgent need for effective treatment strategies. The primary treatment consideration was addressing diverse pathophysiological mechanisms (58.0%), indicating a preference for a comprehensive approach.

Beta blockers, particularly Carvedilol (58.8%), were the most preferred initial treatment (49.6%), reflecting their perceived efficacy and safety. ARBs, especially Telmisartan (93.1%), were also highly favored due to their 24-hour blood pressure control and superior cardiovascular outcomes. Most physicians (87.1%) advocated for dual combination therapy, with the S-Metoprolol and Telmisartan combination being the top choice, especially for patients with tachycardia (46.5%). This combination was praised for its cardiovascular benefits (41.1%), rapid blood pressure reduction, and excellent tolerability, with 86% of physicians rating its safety profile as very good to excellent.

Physicians observed significant systolic blood pressure reductions with this combination over four weeks, with most (41.2%) reporting that 25-50% of patients reached their blood pressure goals. The combination was commonly used for periods ranging from six months to over five years, demonstrating its efficacy and long-term tolerability.

These findings underscore the importance of combination therapy in managing hypertension effectively. The preference for S-Metoprolol and Telmisartan highlights their combined benefits in controlling blood pressure and enhancing cardiovascular health. High satisfaction and positive safety ratings suggest this combination is a viable long-term treatment option. Future research should explore the long-term impacts and patient-specific responses to optimize hypertension management strategies further.

8 CLINICAL RECOMMENDATIONS

- Initiate early combination therapy using Beta blockers and ARBs in hypertensive patients, particularly those with multiple risk factors or elevated baseline blood pressure.
- Customize treatment choices based on individual patient factors such as comorbidities, cardiovascular risk profile, and tolerability, favoring beta blockers like carvedilol and ARBs such as telmisartan when appropriate.
- Monitor blood pressure and cardiovascular parameters regularly to assess the effectiveness of beta blocker and ARB combinations.
- Adjust treatment to achieve target blood pressure goals and optimize cardiovascular outcomes.
- Start dual combination therapy with beta blockers and ARBs as initial therapy for hypertensive patients who do not achieve adequate blood pressure control with monotherapy.
- Educate patients on the benefits of beta blockers and ARBs in managing hypertension and reducing cardiovascular risks.
- Stress the importance of adherence to therapy for long-term benefits.
- Monitor patients closely for potential side effects related to beta blockers (e.g., bradycardia, fatigue) and ARBs (e.g., hyperkalemia).

- Manage adverse effects promptly to enhance patient comfort and adherence.
- Consider the sustained use of beta blocker and ARB combinations in patients who respond well and tolerate therapy effectively.
- Regularly review treatment plans to ensure continued efficacy and safety over extended periods.
- Promote collaborative care among patients, healthcare providers, and specialists (e.g., cardiologists) to optimize hypertension management.
- Facilitate shared decision-making and coordinated care to achieve improved patient outcomes.

9 CONSULTANT OPINION

Conduct randomized controlled trials to compare the efficacy of Beta blocker and ARB combinations with alternative antihypertensive therapies. Investigate the longterm cardiovascular outcomes, renal function, and overall mortality associated with Beta blocker and ARB combination therapy in hypertensive patients. Perform subgroup analyses to identify patient groups that may derive maximum benefit from this treatment approach, considering factors such as age, cardiovascular risk profile, and presence of comorbidities. Collect real-world data to complement clinical trial findings, providing insights into the real-world effectiveness and safety of Beta blocker and ARB combinations across diverse clinical settings. Additionally, assess patient-reported outcomes to evaluate the impact of Beta blocker and ARB therapy on quality of life, treatment adherence, and patient satisfaction. Addressing these aspects will enhance our understanding of the therapeutic potential and optimal use of Beta blocker and ARB combinations in hypertension management, guiding more tailored and effective treatment strategies for patients.

10 MARKET OPPORTUNITIES

The combination therapy of Beta blockers and ARBs presents a significant market opportunity in hypertension management, particularly in India. With a substantial percentage of patients experiencing uncontrolled blood pressure despite initial treatment, there exists a clear demand for more effective therapeutic options. The survey highlights a strong preference among physicians (87.1%) for dual combination therapy, underscoring a ready market that is poised for expansion. Given that 52.7% of physicians report a significant proportion of patients requiring initiation with dual therapy, there is a clear market need for therapies that can achieve robust blood pressure control from the outset.

Beta blockers and ARBs are particularly favored for their synergistic effects in managing hypertension, including cardiovascular benefits and reduced risk of adverse events like hypokalemia and bradycardia. The combination's excellent safety profile, as perceived by 85.1% of physicians, further enhances its market appeal as a reliable long-term treatment option. By targeting specific patient populations such as those with high cardiovascular risk or multi-comorbidities, this therapy can position itself as a specialized solution for challenging cases of hypertension.

The therapy's potential to improve patient adherence and long-term outcomes also presents a compelling opportunity for market penetration and growth. By emphasizing its efficacy in achieving target blood pressure goals and enhancing overall cardiovascular health, Beta blocker and ARB combinations can capture a significant share of the hypertensive treatment market, addressing a critical healthcare need while offering substantial commercial potential.

11 MARKET POSITIONING

Advanced Hypertension Management Solution

Position Beta blocker and ARB combinations as the advanced choice in hypertension management, addressing unmet needs where monotherapy falls short. Highlight their superior efficacy in achieving target blood pressure control, especially in patients requiring dual therapy initiation due to severe hypertension or multiple risk factors.

Optimized for High-Risk Patients

Market the therapy as optimized for high-risk patients, including those with resistant hypertension, high cardiovascular risks, and complex comorbidities. Emphasize its tailored benefits such as improved cardiovascular outcomes and reduced risk of

complications, making it ideal for challenging cases where stringent blood pressure control is critical.

Physician-Preferred Solution

Leverage the strong preference and endorsement of Beta blocker and ARB combinations by physicians (87.1%) to establish credibility and trust. Showcase widespread adoption and positive feedback from the medical community, reinforcing its efficacy and safety profile in clinical practice.

Enhanced Long-Term Health Management

Promote the combination's excellent safety profile and potential for long-term adherence, distinguishing it from other therapies. Highlight benefits such as reduced risk of adverse events like hypokalemia and bradycardia, and emphasize its role in supporting sustained patient compliance and improved long-term health outcomes.

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